# **Complete Summary**

## **GUIDELINE TITLE**

Attaining optimal asthma control: a practice parameter.

# BIBLIOGRAPHIC SOURCE(S)

Joint Task Force on Practice Parameters. Attaining optimal asthma control: a practice parameter. J Allergy Clin Immunol 2005 Nov; 116(5): S3-11. [49 references] PubMed

#### **GUIDELINE STATUS**

This is the current release of the guideline.

## \*\* REGULATORY ALERT \*\*

## FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On November 18, 2005, the U.S. Food and Drug Administration (FDA) notified manufacturers of Advair Diskus, Foradil Aerolizer, and Serevent Diskus to update their existing product labels with new warnings and a Medication Guide for patients to alert health care professionals and patients that these medicines may increase the chance of severe asthma episodes, and death when those episodes occur. All of these products contain long-acting beta2-adrenergic agonists (LABA). Even though LABAs decrease the frequency of asthma episodes, these medicines may make asthma episodes more severe when they occur. A Medication Guide with information about these risks will be given to patients when a prescription for a LABA is filled or refilled. See the <u>FDA Web site</u> for more information.

# COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

# IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

# SCOPE

# DISEASE/CONDITION(S)

Asthma

## **GUIDELINE CATEGORY**

Evaluation Management Treatment

# CLINICAL SPECIALTY

Allergy and Immunology Family Practice Internal Medicine

## INTENDED USERS

Health Care Providers Physicians

# GUIDELINE OBJECTIVE(S)

To provide physicians and other health professionals with a practical guide for attaining optimal asthma control

#### TARGET POPULATION

Patients with asthma

## INTERVENTIONS AND PRACTICES CONSIDERED

## Evaluation/Assessment

- 1. Assessment of asthma control including frequency of symptoms; frequency of rescue bronchodilator; frequency of night/morning symptoms; activity, work, and school limitations; pulmonary function tests
- 2. Periodic assessments of asthma including psychosocial status, adherence/compliance, medication's side effects, asthma triggers, and reviewing of asthma action plan

# Management/Treatment

- 1. Maintaining or stepping-down therapy (in well-controlled asthma)
- 2. Stepping-up therapy (in not well-controlled asthma)

- 3. Pharmacotherapy including
  - Short-acting beta-agonist as needed
  - Low-dose inhaled corticosteroids (ICSs), leukotriene modifiers, theophylline, cromolyn, or nedocromil
  - Low-dose/medium-dose ICSs plus inhaled long-acting beta-agonist (LABA) or medium-dose ICSs; low-dose/medium-dose ICSs plus either leukotriene modifier or theophylline
  - High-dose ICSs and LABA plus systemic corticosteroids if needed (consider monoclonal anti-IgE)

#### MAJOR OUTCOMES CONSIDERED

- Values of peak expiratory flow (PEF) and forced expiratory volume in one second (FEV<sub>1</sub>)
- Quality of life
- Emergency department use and hospitalizations for asthma

#### METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The development of these practice parameters included a MEDLINE search using the key words "asthma control" with selection of articles on the basis of expert opinion.

## NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

La Evidence from meta-analysis of randomized controlled trials

Ib Evidence from at least one randomized controlled trial

II a Evidence from at least one controlled study without randomization

IIb Evidence from at least one other type of quasi-experimental study

III Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, and case-control studies

IV Evidence from expert committee reports, opinions or clinical experiences of respected authorities, or both

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Published clinical studies or reports were rated by category of evidence and used to establish the strength of the clinical recommendations.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In 1991, the National Heart, Lung, and Blood Institute (NHLBI) published its first set of guidelines for the diagnosis and management of asthma. This publication introduced the concept of classification of asthma by asthma severity (mild, moderate, and severe) and linked asthma severity to a stepwise guide to pharmacotherapy of asthma. "Attaining optimal asthma control: a practice parameter" builds on the foundation of the NHLBI asthma report and extends the concept of guideline-driven asthma management.

Asthma management driven by assessment of asthma control emphasizes and operationalizes the goals of asthma therapy, as originally listed in the NHLBI Expert Panel Report. Assessment and targets of asthma control also builds on the step-up and step-down guideline, as recommended in the NHLBI report. Perhaps more importantly, control-driven asthma guidelines encompass the principles of chronic disease management, including periodic assessment, goal (outcome) orientation, and individualization of therapy.

# RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

- A. Directly based on category I evidence
- B. Directly based on category II evidence or extrapolated recommendation from category I evidence
- C. Directly based on category III evidence or extrapolated recommendation from category I or II evidence
- D. Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence

NR Not rated

# **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

Guideline recommendations are presented in the form of summary statements. After each statement is a letter that indicates the strength of the recommendation. Grades of recommendations (A-D, Not rated) and levels of evidence (Ia, Ib, IIa, IIb, III, IV) are defined at the end of the "Major Recommendations" field.

# Summary Statements

# Asthma Severity and Asthma Control

- 1. Asthma symptoms do not always correlate with asthma severity. There are limitations to classifying asthma severity in patients already being treated. (B)
- 2. Management based on asthma control encompasses the principles of chronic disease management, including periodic assessment, goal (outcome) orientation, and individualization of therapy. (B)

## Goals of Asthma Treatment

- Prevent chronic and troublesome symptoms
- Maintain (near-) normal pulmonary function
- Maintain normal activity levels
- Prevent recurrent exacerbations of asthma
- Provide optimal pharmacotherapy with minimal or no adverse effects
- Meet patients' and families' expectations

# Definition of Well-Controlled Asthma

- Asthma symptoms twice a week or less
- Rescue bronchodilator use twice a week or less
- No nighttime or early morning awakening
- No limitations on exercise, work, or school
- Well-controlled asthma by patient and physician assessment
- Normal or personal best peak expiratory flow (PEF) or forced expiratory volume in one second (FEV<sub>1</sub>)

## Assessment of Asthma Control

- 3. Asthma control can be expected to change over time. Asthma control should be assessed at every clinical encounter for asthma, and management decisions should be based on the level of asthma control. (B)
- 4. Asthma control is based on asthma symptoms, sleep disturbance, use of rescue medication, limitations of daily activity, patient and physician overall assessment, and lung function. (A)
- 5. Asthma should be considered well controlled if (1) asthma symptoms are twice a week or less; (2) rescue bronchodilator medication is used twice a week or less; (3) there is no nocturnal or early morning awaking; (4) there are no limitations of work, school, or exercise; (5) the patient and physician consider their asthma well controlled; and (6) the patient's peak expiratory flow (PEF) or forced expiratory volume in one second (FEV<sub>1</sub>) is normal or his or her personal best. (B)
- 6. Complete or total control of asthma can be defined as (1) no asthma symptoms; (2) no rescue bronchodilator use; (3) no nighttime or early morning awakening; (4) no limitations on exercise, work, or school; (5) complete control of asthma by patient and physician assessment; and (6) normal or personal best PEF or FEV<sub>1</sub>. (A)
- 7. In addition to the assessment of asthma control, there are several important activities that should be accomplished during the periodic visit for asthma, including assessment of psychosocial status, assessment of adherence-compliance, assessment of medication use and side effects, assessment of asthma triggers, review of written asthma action plan (as appropriate), and confirmation of asthma diagnosis. (B)

# Step Care Based on Asthma Control

- 8. A patient's asthma control for a specific clinical encounter should be determined as well controlled or not well controlled. (B)
- 9. A more detailed assessment of asthma should be conducted, especially for patients whose asthma is not well controlled. (B)
- 10. The step care of asthma should be based on asthma control. (A)

# Simplified Guidelines for the Pharmacotherapy of Asthma

- Step 1 -- Short-acting beta-agonist as needed (indicated for all patients)
- Step 2 -- Low-dose inhaled corticosteroids (ICSs), leukotriene modifiers, theophylline, cromolyn, or nedocromil
- Step 3 -- Low-dose/medium-dose ICSs plus inhaled long-acting beta-agonist (LABA) or medium-dose ICSs; low-dose/medium-dose ICSs plus either leukotriene modifier or theophylline
- Step 4 -- High-dose ICSs and LABA plus systemic corticosteroids if needed (consider monoclonal anti-IgE)

## Physician's Role in Attaining Asthma Control

11. Asthma management driven by level of asthma control demands a close partnership between physician and patient. (B)

# **Definitions**:

# Category of Evidence

- La Evidence from meta-analysis of randomized controlled trials
- Ib Evidence from at least one randomized controlled trial
- II a Evidence from at least one controlled study without randomization
- II b Evidence from at least one other type of quasi-experimental study
- III Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
- IV Evidence from expert committee reports, opinions or clinical experiences of respected authorities, or both

# Strength of Recommendation

- A. Directly based on category I evidence
- B. Directly based on category II evidence or extrapolated recommendation from category I evidence
- C. Directly based on category III evidence or extrapolated recommendation from category I or II evidence
- D. Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence

NR Not rated

## CLINICAL ALGORITHM(S)

"Algorithm for Attaining Optimal Asthma Control" is provided in the original guideline document.

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each summary statement (see "Major Recommendations" field).

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Improved asthma control

#### POTENTIAL HARMS

Adverse effects of pharmacotherapy

# QUALIFYING STATEMENTS

## QUALIFYING STATEMENTS

This is a complete and comprehensive document at the current time. The medical environment is a changing environment, and not all recommendations will be appropriate for all patients. Because this document incorporated the efforts of many participants, no single individual, including those who served on the Joint Task Force, is authorized to provide an official American Academy of Allergy, Asthma, and Immunology (AAAAI) or American College of Allergy, Asthma, and Immunology (ACAAI) interpretation of these practice parameters. Any request for information about or an interpretation of these practice parameters by the AAAAI or ACAAI should be directed to the Executive Offices of the AAAAI, the ACAAI, and the Joint Council of Allergy, Asthma, and Immunology. These parameters are not designed for use by pharmaceutical companies in drug promotion.

# IMPLEMENTATION OF THE GUIDELINE

## DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## IMPLEMENTATION TOOLS

Clinical Algorithm

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Getting Better Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

# IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

Joint Task Force on Practice Parameters. Attaining optimal asthma control: a practice parameter. J Allergy Clin Immunol 2005 Nov; 116(5): S3-11. [49 references] PubMed

#### **ADAPTATION**

This practice parameter builds on the foundation of the National Heart. Lung, and Blood Institute (NHLBI) asthma report, National Asthma Education and Prevention Program. Expert Panel Report: guidelines for the diagnosis and management of asthma. Bethesda (MD): National Institutes of Health Publication No. 91-3642. 1991.

#### DATE RELEASED

2005 Nov

# GUIDELINE DEVELOPER(S)

American Academy of Allergy, Asthma and Immunology - Medical Specialty Society

American College of Allergy, Asthma and Immunology - Medical Specialty Society Joint Council of Allergy, Asthma and Immunology - Medical Specialty Society

#### **GUIDELINE DEVELOPER COMMENT**

These parameters were developed by the Joint Task Force on Practice Parameters, representing the American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology.

#### SOURCE(S) OF FUNDING

Funded by the American Academy of Allergy, Asthma, and Immunology (AAAAI), the American College of Allergy, Asthma, and Immunology (ACAAI), and the Joint Council of Allergy, Asthma and Immunology (JCAAI).

#### **GUIDELINE COMMITTEE**

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

- J. Li had consultant arrangements with Roche, Novartis, and Glaxo; has received grants from Astra Zeneca, Glaxo, and Schering; and has received honoraria from Merck, Astra Zeneca, and Glaxo.
- L. Bernstein has stock in Glaxo.
- J. Oppenheimer has consultant arrangements with Sepracor, Glaxo, Astra Zeneca, and Roche; has received grants from Sepracor, Glaxo, Astra Zeneca, Schering Sanofi, Boehringer Ingelheim, and Merck; and is on the speaker's bureau for Sepracor, Glaxo, Schering Sanofi, and Boehringer Ingelheim.

This parameter was edited by Dr Nicklas in his private capacity and not in his capacity as a medical officer with the Food and Drug Administration. No official support or endorsement by the Food and Drug Administration is intended or should be inferred.

#### **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the <u>Joint Council of Allergy, Asthma, and Immunology (JCAAI) Web site</u>.

Print copies: Available from JCAAI, 50 N. Brockway, Ste 3-3 Palatine, IL 60067

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI on January 16, 2006. The information was verified by the guideline developer on February 21, 2006.

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